

## **REMARKS/ARGUMENTS**

Claims 1, 3-16, and 18-28 remain in the application. Claims 1, 5, 16, and 20 have been amended. Reconsideration of this application, as amended, is respectfully requested.

Claims 1 and 16 have been amended to specify that at least one enzyme or substrate for an enzyme, or at least one mediator is incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode. Support for this amendment can be found at page 5, lines 7-15 of the specification, at page 13, lines 1-9 of the specification, at page 23, lines 7-21 of the specification, at page 13, lines 20-23 of the specification for the substrate feature, and in Table 1 (page 12) of the specification. Please note the use of the term "or" rather than the term "and." Claims 5 and 20 have been amended to specify that at least one layer comprising (i) at least one enzyme or substrate for an enzyme and (ii) at least one mediator overlies the working electrode. Support for this amendment can be found at page 9, lines 10-14 of the specification. Support for this amendment can be found at page 13, lines 10-20 of the specification and at page 13, lines 20-23 of the specification for the substrate.

Further support for these changes finds authority in In re Wertheim, 191 USPQ 90 (CCPA) 1976) at 97, wherein it is stated:

.....That what appellants claim as patentable to them is less than what they describe as their invention is not conclusive if their specification also reasonably describes that which they do claim. Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable. As we said in a different context in In re Saunders, 58 CCPA 1316, 1327, 44 F. 2d 599, 607, 170 USPQ 213, 220 (1971):

To rule otherwise would let form triumph over substance, substantially eliminating the right of an applicant to retreat to an

otherwise patentable species merely because he erroneously thought he was first with the genus when he filed. Cf. In r Ruff, 45 CCPA 1037, 1049, 256 F. 2d 590, 597, 188 USPQ 340, 347 (1958). Since the patent law provides for the amendment during prosecution of *claims*, as well as the specification supporting claims 35 USC 132, it is clear that the reference to "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention" in the second paragraph of 35 USC 112 does not prohibit the applicant from changing what he "regards as the invention" (i.e., the subject matter on which he seeks patent protection) during the pendency of his application.....

Claims 1 and 16 were rejected under 35 U. S. C. §112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed for the following reasons.

The amendments to claim 1 and 16 address the Examiner's comment on page 3 of the Office Action. As currently amended, claims 1 and 16 recite:

(a) at least one enzyme or substrate for an enzyme incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode; or

(b) at least one mediator incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode.

In view of these changes, claims 1 and 16 comply with the written description requirement.

Claims 5 and 20 were rejected under 35 U. S. C. §112, first paragraph, as failing to comply with the enablement requirement. This rejection is respectfully traversed for the following reasons.

Claims 5 and 20 have been amended to adopt the interpretation made by the Examiner in the last three lines of page 4 of the Office Action. For this reason, claims 5 and 20 comply with the enablement requirement.

Claims 1 and 16 were rejected under 35 U. S. C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed for the following reasons.

Claims 1 and 16 have been amended to clearly point out which substances can be located in the various locations of the biosensor. Furthermore, the term "reagent" has been deleted and been replaced by the enzyme, substrate for an enzyme, or mediator, as required. Accordingly, the requirements of 35 U. S. C. §112, second paragraph, are satisfied.

Claims 1, 3-5, 8, and 10 were rejected under 35 U. S. C. §102 (b) as being anticipated by U. S. Patent No. 5,795,453 to Gilmartin. This rejection is respectfully traversed for the following reasons.

Gilmartin, U. S. Patent No. 5,795,453 (hereinafter "Gilmartin"), was described on page 13-14 of the Amendment and Response under 37 CFR 1.116 filed 13 June 2005.

Gilmartin discloses the use of an enzyme and a mediator in the conductive track leading from the working electrode to the electrical contact associated with the working electrode. In contrast to Gilmartin, the claims of the present application recite that at least one enzyme or substrate for an enzyme or at least one mediator is incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode. According to the claims of the present application, the enzyme or substrate is not mixed with the mediator to prepare the substance that is incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode. The benefit of the biosensor described in the present application is described at page 23, lines 7-21 of the specification, where it is stated:

In situations where the mediator is known to interact with the enzymes, the mediator and the enzyme must be separated during the preparation of the ink. For example, quinones are known to react with glucose dehydrogenase enzymes, but quinone mediators are desirable because they allow the use of lower voltage for measurement. Accordingly, physical separation of these quinone mediators from the enzyme before the start of the assay is desired. This invention allows the use of, for example, a phenanthroline quinone (PQ) mediator, e.g., 4,7-phenanthroline-5,6-dione, with a quinoprotein enzyme, e.g., pyrroloquinoline quinone, as a co-enzyme. In solution, the quinoprotein enzyme interacts with the PQ mediator, resulting in inactivation of the enzyme. Embedding the PQ mediator in the conductive track enables the use of the quinoprotein enzyme – PQ mediator combination for the measurement of analyte such as glucose. In a conventional biosensor, this enzyme – mediator combination would have resulted in inactivation of the enzyme, unless steps have been taken to isolate enzyme from the mediator.

In view of the differences between the conductive track described in Gilmartin and the conductive track recited in claim 1 and the claims depending from claim 1, and in view of the unexpected benefit brought about by the construction of the conductive track described in the claims of the present application, it is submitted that Gilmartin does not anticipate claims 1, 3-5, 8, and 10 of this application, and, furthermore, does not render these claims obvious to one of ordinary skill in the art.

Claims 1, 3-16, and 18-28 were rejected under 35 U. S. C. §103 (a) as being unpatentable over Feldman et al. in view of Gilmartin. This rejection is respectfully traversed for the following reasons.

Feldman et al., U. S. Patent No. 6, 299,757 (hereinafter "Feldman et al."), was described on page 15 of the AMENDMENT AND RESPONSE filed December 13, 2004.

This ground of rejection relies on Gilmartin to supply the deficiencies of Feldman et al. However, as stated previously with respect to the anticipation

rejection, Gilmartin discloses the use of an enzyme and a mediator in the conductive track leading from the working electrode to the electrical contact associated with the working electrode. The claims of the present application recite that at least one enzyme or substrate for an enzyme or at least one mediator incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode. According to the claims of the present application, the enzyme or substrate is not mixed with the mediator to prepare the substance that is incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode. These differences, in combination with the previously cited unexpected benefit, cause Gilmartin to fail to remedy the deficiencies of Feldman et al. In view of the differences between the conductive track described in Gilmartin and the conductive track recited in claims 1 and 16, and the claims depending from claims 1 and 16, and in view of the unexpected benefit brought about by the construction of the conductive track described in the claims of the present application, it is submitted that the combination of Feldman et al. and Gilmartin fails to render claims 1, 3-16, and 18-28 obvious to one of ordinary skill in the art.

Claims 1, 3, 4, 10, 12, 13, and 15 were rejected under 35 U. S. C. § 103 (a) as being unpatentable over Hughes in view of Gilmartin. This rejection is respectfully traversed for the following reasons.

Hughes et al., U. S. Patent No. 6,129,823 (hereinafter "Hughes et al."), was described on page 15 of the AMENDMENT AND RESPONSE filed December 13, 2004.

Hughes et al. et al. does not disclose or suggest that at least one enzyme (or substrate for an enzyme), or at least one mediator, is incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode or the electrical contact associated with the working electrode. In Hughes et al., the reagents are deposited over the electrodes only.

Claim 1 of the present application specifies that at least one enzyme (or substrate) or at least one mediator is incorporated in at least one of the

first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode. Thus, the claims of the present application describe a biosensor where at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode or the electrical contact associated with the working electrode contains at least one enzyme (or substrate for an enzyme) or at least one mediator.


As stated previously, Gilmartin discloses the use of an enzyme and a mediator in the conductive track leading from the working electrode to the electrical contact associated with the working electrode. The claims of the present application recite that at least one enzyme or substrate for an enzyme or at least one mediator incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode. According to the claims of the present application, the enzyme or substrate is not mixed with the mediator to prepare the substance that is incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode, or the electrical contact associated with the working electrode. These differences, in combination with the previously cited unexpected benefit, cause Gilmartin to fail to remedy the deficiencies of Hughes et al. For these reasons, it is submitted the combination of Hughes et al. and Gilmartin fails to render claim 1 obvious to one of ordinary skill in the art. Claims 3, 4, 10, 12, 13, and 15 depend either directly or indirectly from claim 1. Accordingly, the combination of Hughes et al. and Gilmartin fails to render claims 1, 3, 4, 10, 12, 13, and 15 obvious to one of ordinary skill in the art.

In view of the foregoing, it is submitted that claims 1, 3-16, and 18-28, as amended, are in condition for allowance, and official Notice of Allowance is respectfully requested.

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